

**I. EXAMINER'S REMARKS**

Claims 1-5 and 11-19 are pending and under examination. The Examiner provides a number of rejections listed herein in the order in which they are addressed:

The Examiner states "Claims 1-5, 11-19 are rejected under 35 U.S. C. 112, second paragraph, as [allegedly] being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention."

The Examiner states that "Claims 1, 12, 14, 15, and 17 [are rejected under 35 U.S. C. 112, second paragraph] are [allegedly] vague and indefinite ... ."

**II. APPLICANT'S REMARKS**

**The Invention is defined**

Claims 1-5 and 11-19 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Specifically, the Examiner states "Each of the claims comprises the term "mini-Adenovirus," the metes and bounds of which are unclear." The Applicants respectfully disagree.

The MPEP and Federal Circuit case law have made it clear that the definiteness of claim language must be analyzed, not in a vacuum, but in light of: 1) the content of the particular application's disclosure; 2) the teachings of the prior art; and 3) the claim interpretation that would be given by one possessing the ordinary level of skill in the art at the time the invention was made. (MPEP § 2173.02). See also *In re Marosi*, 218 USPQ 289 (Fed. Cir. 1983); *Rosemount, Inc. v. Beckman Instruments, Inc.*, 221 USPQ 1 (Fed. Cir. 1984); and *W.L. Gore & Associates, Inc. v. Garlock, Inc.* 220 USPQ 303 (Fed. Cir. 1983). Applicants submit that application of this analysis leads to the conclusion that the Claims are definite. In particular, the Examiner's attention is drawn to the extensive description of mini-Adenovirus on pages 36-44 of the specification.

However, in order to further their business interests and the prosecution of the present application, yet without acquiescing to the Examiner's arguments, Applicants have amended Claims 1-5 and 11-19 by deleting "mini-Adenovirus" and replacing it with "recombinant

vector". Applicants reserve the right to prosecute the original, or similar claims in the future. These Amended Claims do not add new matter.

The Applicants point out the following support for the inserted term "recombinant vector" within the specification:

"[0028] The term "**recombinant vector**" as used herein refers to a nucleic acid molecule which is capable of transferring nucleic acid sequences contained therein into a cell, and which is produced by means of molecular biological techniques.

**Recombinant vectors are exemplified by linear DNA, plasmid DNA, viruses, etc."**

These amended claims particularly point out and distinctly claim the subject matter that the Applicants view as their invention. Thus, the presently claimed invention is definite and should be passed into allowance.

Additionally, the Examiner states "Claims 1, 12, 14, 15, and 17 are vague and indefinite in that the metes and bounds of the phrase "wherein said first vector lacks a second adeno-associated virus terminal repeat sequence" are unclear. The Examiner argued that it is not clear whether "the phrase mean[s] that the entire adeno-associated virus terminal repeat sequence is missing or that only a portion of the adeno-associated virus terminal repeat sequence is missing." Office Action, page 3, last paragraph. However, the Examiner appears to have inadvertently missed the Specification's express definition of the term "**lacks**," which teaches that:

"[0035] The terms "lack" and "lacking" a nucleotide sequence when made in reference to a vector **means that the vector contains at least one deletion** (*i.e.*, absence of one or more nucleotides) in the nucleotide sequence. Deletions may be **continuous** (*i.e.*, uninterrupted) or **discontinuous** (*i.e.*, interrupted). Deletions may lie in a coding sequence or a regulatory sequence. A deletion can be a **partial deletion** (*i.e.*, involving removal of a portion ranging in size from one (1) nucleotide residue to the entire nucleic acid sequence minus one nucleic acid residue) or a **total deletion** of the nucleotide sequence. Deletions are preferred which prevent the production of at least one expression product encoded by the nucleotide sequence. For example, a vector which lacks an adenovirus E1 gene region refers to a vector which contains at least

one deletion in the E1 gene region. Preferably, though not necessarily, the deletion prevents the production of at least one of the multiple proteins encoded by the E1 gene region. (see original Specification, paragraph bridging pages 15 and 16).

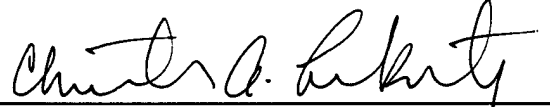
In view of the Specification's express definition of the term "lacks" as encompassing both partial and complete deletions, as well as continuous and discontinuous deletions, there can be no ambiguity to one of ordinary skill in the art as to the meaning of this term.

Accordingly, the rejection of claims 1, 12, 14, 15, and 17 should be withdrawn.

### CONCLUSION

Applicants believe that the arguments set forth above traverse the Examiner's rejections and therefore request that these grounds for rejection be withdrawn for the reasons set forth above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned.

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